

**REMARKS**

**I. Summary of the Office Action and this Reply**

Claims 1-11, 13-16 and 28-31 are pending in the application. Claims 12, 17-27 and 32-53 have been withdrawn.

The Examiner has rejected claims 1-5 and 28-30 under U.S.C. § 103(a) , asserting that such claims are anticipated by U.S. Patent No. 5,267,963 to Bachynsky ("Bachynsky") in view of U.S. Patent No. 3,340,626 to Bergman ("Bergman"). The Examiner has rejected claims 6, 7 and 31 under 35 U.S.C. § 103(a), asserting that such claims are obvious over Bachynsky in view of Bergman and U.S. Patent No. 5,201,716 to Richard ("Richard"). Claims 8-11 and 13-16 stand rejected under 35 U.S.C. § 103(a) over various combinations of Bachynsky, Bergman, Richard, Wozencroft publication WO/93/01851 ("Wozencroft") and U.S. Patent No. 4,894,054 to Miskinyar ("Miskinyar").

In this Reply, claims 28 and 31 are amended. No new matter is added.

**II. The Final Rejection Is Premature and Should Be Withdrawn**

The finality of the outstanding Office Action is premature and should be withdrawn because of the inclusion of section 103 rejections relying on Bergman. The MPEP provides that a second action on the merits shall be final "except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)." MPEP 706.07(a).

In the present case, the Examiner has withdrawn a previous rejection of claims 1, 28 and others and introduced a new ground of rejection, namely a section 103(a) rejection over a combination of art that includes Bergman, which is newly cited art. This new ground of rejection is not based on information submitted in an Information Disclosure Statement.

Accordingly, MPEP 706.07(a) requires that the new ground of rejection be necessitated by applicant's amendment. But, applicant's only substantive amendments in its last Reply were to claim 1 (in which "upon releasing the base" was amended to "responsive to releasing the base") and claim 28 (in which "in response to removal of the base from the surface" was added to the claim.) It is noted that at least one definition of "upon", as provided in Webster's Ninth New collegiate Dictionary (1984), is "thereafter, thereon." A proper search of the original claims would have included a search for art relating to the language of the amended claims. Accordingly, the claim amendments did not necessitate a new ground of rejection, a new search, or newly cited art, and the finality of the Action is premature.

Applicants have not yet had an opportunity to substantively respond or amend in view of Bergman. The Examiner is reminder of MPEP §706.07, which provides that:

present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application . . . The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal.

Reconsideration and withdrawal of the finality of the Action are requested

respectfully.

### **III. Response to 103 Rejections**

The Examiner has rejected claims 1-11, 13-16 and 28-31 under U.S.C. § 103(a).

A section 103 rejection is proper only if all claim limitations are taught or suggested by the cited art. MPEP §2143.

#### **Claims 1 and 28**

Independent claim 1 is directed to a needle device including a housing having a base for placement against a surface of a needle penetrating site. The needle device includes "a retraction mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface."

Bachynsky discloses a medication injection device including a sliding cam mechanism that is advanced by a resiling spring. As noted by the Examiner, Bachynsky fails to disclose a retraction mechanism that moves a needle to a retracted position responsive to releasing a base from a site surface. Applicants agree.

Citing Figures 1-3 and col. 2, lines 2 and 28, the Examiner asserts that Bergman discloses a needle-based injection device that includes a retraction mechanism that moves the needle to the retracted position responsive to releasing the base from the site surface. Applicants respectfully disagree.

Bergman discloses a self-triggered veterinary attachment that includes a piston 23 biased by a coil spring 15. As the piston 23 moves, fluid is injected via a needle 20. Contrary to the Examiner's assertion that Bergman discloses "a retraction mechanism

that moves the needle to the retracted position", the needle 20 in Bergman's device does not move at all; it is fixed in position relative to the device/shaft 27' by way of a set screw 27. That the needle is fixed, and that the piston 23 moves relative to the needle, is apparent from a careful study of Figures 1 and 2. Accordingly, Bergman does not disclose any retraction of the needle, and thus cannot disclose a needle retraction mechanism that is responsive to releasing of a base from a site surface. For at least these reasons, reconsideration and withdrawal of the rejection of claim 1 are requested respectfully.

Regarding the Examiner's citation of Figures 1-3, it is noted that Bergman discloses a trigger 3' terminating in a contact head 16. The contact head 16 is axially biased by a compression spring 32. The trigger 3' is supported by a trigger mount 3 within trigger guides 4 and 5. This arrangement permits linear (axial) sliding movement of the trigger 3' relative to the device as an animal's body, etc. is pressed against the contact head 16 to compress spring 32. The linear movement of the trigger 3' causes pivoting of a separate lever 7, which in turn causes a trigger stop, e.g. 11, to release a cocking lug 14 and to permit the piston 23 to move to deliver the injection dose. Upon withdrawal of the device, spring 32 relaxes, extending contact head 16. The needle 20 never moves. Accordingly, the needle 20 is never moved to a retracted position, responsive to release from a site surface or otherwise. Further needle 20 is never retracted to a position within any housing.

For at least this additional reason, reconsideration and withdrawal of the rejection of claim 1 are requested respectfully.

Independent claim 28 includes a similar recitation, namely, "a retraction

mechanism that automatically moves the needle from the extended position to the retracted position, the retraction mechanism being configured to begin moving the needle to the retracted position in response to removal of the base from the surface."

For reasons similar to those set forth above, this element is neither taught nor suggested by Bachynsky and/or Bergman.

For at least these reasons, reconsideration and withdrawal of the rejection of claims 1 and 28 are requested respectfully.

#### **Claims 2-3 and 29-30**

Claim 2-3 and 29-30 depend from claims 1 and 28, respectively, and are likewise patentable for at least these reasons.

#### **Claims 4-7**

Claims 4-7 depend from claim 1 and are thus allowable as depending from an allowable claim, as discussed above with reference to claim 1.

Further, claim 4 recites that "the retraction mechanism includes a trigger member . . . having a first portion adapted to engage the actuator and a second portion adapted to contact the [needle penetrating] site surface." Claim 5 recites that the trigger member is pivotably mounted to the housing. As recited in claim 1, the actuator is "movably mounted to the housing and movable between an unactuated position in which the needle is in the retracted position and an actuated position in which the needle is in the extended position." The Examiner acknowledges that Bachynsky fails to suggest such a trigger member. Applicants agree.

However, the Examiner asserts on page 4 of the Action that Bergman discloses the claimed trigger member. Applicants respectfully disagree. For the reasons set forth above regarding the stationary nature of the needle, Bergman fails to teach or suggest a trigger member adapted to engage an actuator that is movable between unactuated and actuated positions in which the needle is in retracted and extended positions, respectively.

Further, the portion of Bergman cited by the Examiner, namely, col. 2, line 28, relates to the pivotable lever 7. The lever 7 pivots to release the movable piston 23 to inject an injection dose via the stationary needle 20. However, no portion of the pivotable lever 7 has a portion adapted to contact the needle penetrating site surface. Accordingly, Bergman fails to teach or suggest the claimed trigger member; the pivotable lever 7 of Bergman is not the claimed trigger member.

Further still, Bergman has a principle of operation entirely different from that of the claimed embodiment. The contact head 16 of Bergman, which contacts a needle penetrating site surface, does not pivot, and does not engage the actuator. Thus, the contact head 16 and trigger 3' cannot be interpreted to be the claimed trigger member.

Accordingly, Bergman does not cure the deficiencies of Bachynsky, and Bachynsky and Bergman, alone or in combination, fail to teach or suggest all claim elements. For at least these additional reasons, reconsideration and withdrawal of the rejection of claims 4 and 5 are requested respectfully.

Claim 6 recites that "the base further includes a second opening through which the second portion of the trigger member is adapted to contact the site surface." The Examiner asserts that Richard "discloses a similar device in which that [sic] the trigger

member (58) has a second portion (62) adapted to contact the site surface." Applicants disagree. No portion of ejector mechanism 50, including retainer bracket arm 62, is adapted to contact an injection site surface. Instead, the needle assembly 18 protrudes beyond the bracket arm 62, etc. For at least this additional reason, reconsideration and withdrawal of the rejection of claim 6 are requested respectfully.

**Claims 8-11 and 13-16**

Claims 8-11 and 13-16 depend from claim 1 and are likewise patentable. Additionally, claim 8 recites that "the guide comprises a substantially U-shaped channel formed in the housing, the U-shaped channel comprising a first substantially vertical guide portion, a second substantially vertical guide portion and a horizontal guide portion connecting lower ends of the first and second vertical portions." Contrary to the Examiner's assertion, this is neither taught nor suggested by the cited art, particularly Figure 11 of Wozencroft.

Further, claim 10 recites that the needle device includes a spring that biases the actuator to the unactuated position, and that the spring has one end fixedly mounted to the actuator and another end fixedly mounted to the base to enable creation of a spring torsional load when the actuator is rotated relative to the base. Claim 11 recites that the spring is torsionally preloaded to rotate the actuator from the first vertical guide portion to the second vertical guide portion through the horizontal guide portion upon moving the actuator to the actuated position. Contrary to the Examiner's assertions on pages 5 and 6, this is neither taught nor suggested by the cited art, and in particular is not taught or suggested by Wozencroft as cited by the Examiner. Instead, Wozencroft

discloses compression springs that the "collar 106 is capable of limited rotation within the recess 107 in the outer sleeve 105, and is provided with an actuating portion in the form of a milled ring 118 which is capable of being manually rotated through a limited angle when the guard is in its extended position in order to unlock the guard." Page 10, lines 23-28. Other embodiments include a similar, manually rotatable, milled ring.

Claims 13-16 depend from claim 11 and are likewise patentable.

For at least these additional reasons, reconsideration and withdrawal of the rejections of claims 8-11 and 13-16 are requested respectfully.

### **Claim 31**

Claim 31 depends from claim 28 and is likewise patentable. In addition, claim 31 requires that the retraction mechanism "includes a cover member for covering the opening after the needle moves from the extended position to the retracted position." The retracted position is a position in which the needle is "in the housing." A needle device according to Claim 28, wherein the retraction mechanism includes a cover member for covering the opening after a tip of the needle moves from the extended position to the retracted position, in which the tip of the needle is received within the housing.

On page 3 of the Action, the Examiner states that Richard discloses a cover member 70 for covering an opening after a needle moves from an extended to a retracted position. This is simply incorrect. Contrary to the Examiner's assertions, Richard does not disclose a base having "a second opening through which the second portion of the trigger member is adapted to contact the site surface." Additionally,



Richard does not teach or suggest "a cover member for covering the opening after a tip of the needle moves from the extended position to the retracted position, in which the tip of the needle is received within the housing."


For at least these additional reasons, reconsideration and withdrawal of the rejection of claim 31 are requested respectfully.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants believe claims 1-11, 13-16 and 28-31 to be patentable and the application in condition for allowance. Applicants respectfully request issuance of a Notice of Allowance. If any issues remain, the undersigned requests a telephone interview prior to the issuance of an action.

Respectfully submitted,

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